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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,843	05/15/2006	Luke Alphey	138-05	5995
23713	7590	11/12/2008	EXAMINER	
GREENLEE WINNER AND SULLIVAN P C 4875 PEARL EAST CIRCLE SUITE 200 BOULDER, CO 80301			GUZO, DAVID	
			ART UNIT	PAPER NUMBER
			1636	
			MAIL DATE	DELIVERY MODE
			11/12/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/562,843	ALPHEY, LUKE	
	<b>Examiner</b>	<b>Art Unit</b>	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 27 June 2008.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-31 is/are pending in the application.  
 4a) Of the above claim(s) 14-18 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-13 and 19-31 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 28 December 2005 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>11/30/07, 2/7/07</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____

**Detailed Action**

**Election/Restriction**

Applicant's election with traverse of Group I, Claims 1-13, 22, 23 and 29-31 in the reply filed on 6/27/08 is acknowledged. The traversal is on the ground(s) that the limitation recited in Claim 14 is also recited in Claim 9 and that therefore the limitation of Claim 14 should be examined with the elected Group. Applicant also indicates that the Group III claims are dependent on Group I and should be examined with Group I. This is not found entirely persuasive because the invention of Group II involves a patentably distinct composition requiring at least 3 inverted repeats while the invention of Group I requires at least four inverted repeats with at least two pairs of opposing pairs of inverted repeats. Group I therefore requires a combination of unique technical features not required by the invention of the Group II. Group III (Claims 24-28) is rejoined and claims 19-21 are also rejoined. Claims 1-13 and 19-31 are under examination.

The requirement is still deemed proper and is therefore made FINAL.

Claims 14-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/27/08.

**Objections to the Specification**

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Hyperlinks are found at least on page 26 of the specification. Applicant is encouraged to review the specification thoroughly to identify and disable any hyperlinks.

The disclosure is also objected to because it does not contain, as a separate section, a “Brief Description of the Drawings”.

### **35 USC 101 Rejections**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 27 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Applicant claims a transformant organism, which the specification indicates can be a mammal, comprising a DNA integrated into the genome by use of the recited transposons. Since the claims encompass a mammal (including a human), the claims read on a transformant human being, which is non-statutory subject matter.

### **35 USC 112, 2<sup>nd</sup> Paragraph Rejections**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 and 19-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (and dependent claims) are vague in the recitation of “**transposon-derived** (emphasis added) repeats **derived from** (emphasis added) said transposable element”. Use of the terms “derived” or “derived from” renders the claims vague in that it is unclear what step(s) are involved in the derivation. It is unclear how closely related to the starting materials the transposon-derived repeats are to the starting repeat sequences.

Claim 7 is vague in the recitation of the phrase “wherein the inverted repeats are homologous”. It is unclear what the elements are homologous to, i.e. are they homologous to each other to some other sequences?

Claim 8 is vague in the recitation of “pairs of homologous inverted repeats”. It is unclear what the elements are homologous to, i.e. are they homologous to each other to some other sequences?

Claim 24 (and dependent claims) are vague in the recitation of “providing conditions suitable to excise **a transposon** (emphasis added) from the genome”. It is unclear what transposon is being excised, i.e. the transposon of claim 1 or some other transposon?

The instant invention is free of the art. The closest art is represented by Amutan et al., WO 98/08960. The prior art does not teach transposable elements comprising

the inverted repeats in the claimed arrangement wherein the repeats can be excised to leave the intervening DNA integrated in the genomic DNA without the presence of flanking transposon repeats.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low, Ph.D., can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 7, 2008

/David Guzo/  
Primary Examiner  
Art Unit 1636